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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,487	10/21/2003	Sakari Kauppinen	50287/007002	8760

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CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT PAPER NUMBER

1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/690,487

Applicant(s)

KAUPPINEN ET AL.

Examiner

Louis V. Wollenberger

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-86, 157-159 and 185 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-86, 157-159, and 185 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Location of the Application

The location of the application has changed. The application is now located in Art Unit 1635 and has been docketed to Examiner Louis V. Wollenberger.

Status of Application/Amendment/Claims

Applicant's response filed 12/4/2006 to the Restriction Requirement mailed 6/30/06 is acknowledged. Applicants have elected Group IV, claims 157-159, drawn to methods of inhibiting gene expression using non-naturally occurring nucleic acids. Also acknowledged are Applicants' amendments to the claims.

With entry of the amendment filed on 12/4/2006, claims 1-86, 157-159, and 185 are pending in the application and subject to restriction, as explained below.

Election/Restrictions

Claims 1-86, 157-159, and 185 are drawn to a multitude of related but distinct methods for inhibiting gene expression using non-naturally occurring nucleic acids. Said methods are distinguished by the specific structural and/or functional features and properties of the non-naturally occurring nucleic acid required for use in each method and by the physical nature of the sites targeted by these nucleic acids. Adding to the complexity of the instant application are the countless variations of the instantly claimed methods and nucleic acids, in which the nucleic

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acids and/or targets may vary, both structurally and functionally. In several cases, the methods now claimed are mutually exclusive (e.g., claims 13 and 14, 26 and 27, and at least parts i-vi of claim 157). On top of all this, are the several Markush-style claims reciting alternative embodiments of specific features that must be present in the different nucleic acids (e.g., claims 60-64 and 73 and 74 to name a few).

Related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the methods have a materially different design, requiring a different and unique nucleic acid, comprising its own unique structure and possessing its own unique properties. For example, Claim 157, the base claim, recites no less than 13 different alternative nucleic acids and nucleic acid populations, or pools, for sequence-specific inhibition of a gene. The nucleic acids and populations thereof are distinct one from the other both structurally and functionally, hybridizing to exon-exon, exon-intron, or intron-intron targets and having distinct physical attributes. (Should applicants state on the record that alternatives vii-ix are species of any one of i-vi, applicants will be entitled to a search and examination of one such species along with one genus of one of i-vi.) Claims 1-9 claim at least 9 of these embodiments separately. Additionally, Applicants claim a vast number and complex array of variants of such nucleic acids and methods of using these nucleic acids in dependent claims 1-86, 158, 159, and 185. Since the structures are materially different in at least their design, such structures and the methods for use thereof are considered distinct.

Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Searching and examining each of these methods in a single application would present a serious burden on the examiner, since each method would require different keyword searches (i.e., different fields of search) and different considerations of the patent and non-patent literature with regard to novelty, obviousness, written description, and enablement.

Therefore, because these inventions are distinct for the reasons given above, and the searches required for each are divergent and not coextensive, and because a search and examination of all of the Inventions in a single application would present a serious burden on the Examiner, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed method for prosecution on the merits to which the claims shall be restricted if no generic or linking claim is finally held to be allowable. Applicant is advised that the election must be limited to a single (1) independent or distinct nucleic acid and non-mutually exclusive method thereof.

Applicant is advised that a reply to this requirement must include a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic or linking claim, applicant will be entitled to consideration of claims to additional species or linked inventions which depend from or otherwise require all the limitations of an allowable generic or linking claim as provided by 37

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CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected method and species thereof. MPEP § 809.02(a).

To be clear, Applicant must elect a single non-naturally occurring nucleic acid or population from claim 157. In turn, Applicant must then elect a single method thereof, with regard to the length(s) of the nucleic acid and target regions, percentage of LNA units, spacing, contiguity, number, position(s), and hybridizing capabilities of LNA units, composition (e.g., universal bases, chemical modification, LNA A or T, and so forth) of the nucleic acid or population.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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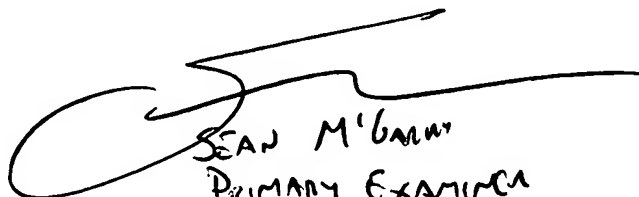
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis V. Wollenberger whose telephone number is 571-272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LVW
Examiner Art Unit 1635
March 10, 2007


SEAN M'GARRY
PRIMARY EXAMINER
AU 1635